

**EXHIBIT 9**



**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

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**In re: Methyl Tertiary Butyl Ether ("MTBE")  
Products Liability Litigation**

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**Master File No. 1:00-1898  
MDL 1358 (SAS)  
M21-88**

**This Document Relates To:**

*City of Fresno v. Chevron U.S.A. Inc., et al.*  
No. 04 Civ. 04973 (SAS)

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**EXPERT REPORT OF WILLIAM S. CAIN, Ph.D.**

**San Diego, California**



Signature

May 2, 2011

Date

EXHIBIT 9

**DISCLOSURE OF WRITTEN REPORT BY EXPERT  
WILLIAM S. CAIN [FRCP 26(2)(B)]**

This written report is submitted in compliance with the disclosure requirements set forth in FRCP 26(2)(B), subject to the right to supplement the report in accordance with FRCP 26(e)(2).

**I. EXPERIENCE AND QUALIFICATIONS**

1. I am currently professor of surgery in the division of otolaryngology - head and neck surgery at the University of California, San Diego, a position I have held since 1994.<sup>1</sup> In that capacity, I oversee the operations of the Chemosensory Perception Laboratory. The Chemosensory Perception Laboratory studies human senses of smell and taste and the physiological and psychological effects of smells and tastes.

2. Before joining the faculty at UCSD, I was a professor of epidemiology (environmental health division) and psychology at Yale University, and was fellow at the John B. Pierce Laboratory, a Yale-affiliated laboratory of environmental health studies.

3. I received my Bachelor of Science at Fordham University in 1963. I then undertook graduate education in experimental psychology at Brown University (Sc.M., 1966; Ph.D., 1968), and I served as a Public Health Service post-doctoral fellow at the Pierce Laboratory from 1967-1969.

4. I have performed research on human chemoreception since 1963 when I became a graduate student. Since my first publication in 1967, I have published more than 250 papers and edited five books on sensory research.<sup>2</sup> My publications are widely and frequently cited. I have

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<sup>1</sup> A copy of my Curriculum Vitae is attached as Exhibit A.

<sup>2</sup> A list of my published articles is included in Exhibit A.

received various honors and prizes, including the Sense of Smell Research Award from the Sense of Smell Institute, the Max Mozell Award for Outstanding Achievement in the Chemical Senses, election to fellow in various national and international societies, and election as president of the Association for Chemoreception Sciences (1983-4) and the New York Academy of Sciences (1986).

3. My involvement with MTBE has come about in several ways:
  - a. In 1993-4, I served as principal investigator on a project concerned with the effects of exposure to an environmentally realistic exposure to airborne MTBE on human comfort and physiology (see Cain, W. S., et al. [1996]. Acute exposure to low-level methyl tertiary-butyl ether (MTBE): Human reactions and pharmacokinetic response. *Inhalation Toxicology*, 8, 21-48.).
  - b. In 1995-6, I served on the Committee on Toxicological and Performance Aspects of Oxygenated Motor Vehicle Fuels for the National Academy of Sciences/National Research Council.
  - c. I testified on chemosensory detection of MTBE in litigation brought by the South Tahoe Public Utility District (Case No. 999128, California Superior Court, San Francisco).<sup>3</sup>
  - d. I testified on chemosensory detection of MTBE in litigation brought by the Fruitridge Vista Water Co. (Case no. AS00535, California Superior Court, Sacramento County).
  - e. I prepared an expert report, and offered testimony, on chemosensory detection of MTBE in litigation brought by United Water New York Inc. (Case no. 04 Civ.

2389, MDL No. 1358) and County of Suffolk and Suffolk County Water Authority (case no. 04 Civ. 5424, MDL No. 1358).

- f. I prepared an expert report, and offered testimony, on chemosensory detection of MTBE in litigation brought by Theodore Garille, executive director, for the Pascoag Utility District (Case No. PCO2-2437), Superior Court, County of Providence, state of Rhode Island).
- g. I prepared an expert report, and offered testimony, on chemosensory detection of MTBE in litigation brought by West Hempstead Water District (Case No. 03 Civ 10052, MDL No. 1358) and Village of Hempstead (Case No. 03 Civ 10055).
- h. I prepared an expert report, and offered testimony, on chemosensory detection of MTBE in litigation brought by a number of individuals in Ft. Montgomery, New York in (Case No. 03 Civ. 8248, MDL No. 1358) (Tonneson).
- i. I have been retained on behalf of Crescenta Valley Water District (Case No. 07 Civ. 9453, MDL No. 1358). My time in this matter is billed at the rate of \$350 per hour plus expenses. These expenses include labor of associates who assist me on the matter.

## II. SUMMARY OF OPINIONS

6. It is my opinion that MTBE can impart a taste and odor to water at concentrations in water of 1 to 2 ppb (1-2 µg/L), and that a substantial number of persons can detect MTBE at those concentrations.<sup>4</sup> Based upon data in the Stocking Study, which I discuss in more detail below, the

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<sup>3</sup> A list of cases in which I have given testimony in 2006-2010 is attached as Exhibit B.

<sup>4</sup> Exhibit C contains a list of documents that I have reviewed and may rely upon depending upon my review of expert opinions and expert depositions. Because discovery is an ongoing process, as additional information is made available, or reviewed by me, I reserve the right to modify,

percentage of people who can detect MTBE at concentrations in water of 1 to 2 ppb is approximately 10%, chance corrected.

### III. DISCUSSION AND BASIS OF OPINIONS

7. My opinions are based upon my review of the studies and documents listed herein, and my extensive education, training, research, and experience in human taste and smell.

8. I have reviewed a number of studies of how well human beings can perceive the odor and flavor of MTBE in water. Various studies support my opinion that MTBE can be detected by a substantial number of persons at concentrations of 1-2 ppb.

9. The principal study that supports my opinion is a 1998 study sponsored by the Oxyfuels Association (an industry organization) and conducted by the environmental consulting firm Malcolm Pirnie and commonly referred to as the Stocking Study. Stocking was first author of a published paper on the study. In this study, 10 of the 57 participants (18%) detected MTBE at concentrations of 2 ppb and above without error. Eighteen of the 57 participants (32%) were able to detect MTBE at concentrations at or below 5 ppb without error. Five ppb equals the Secondary Maximum Contamination Level in California. Individual thresholds reported in the study ranged from 1.4 ppb to 132.3 ppb. The study followed ASTM method E679 protocols and I consider the results to be generally reliable. A copy of the Stocking Study is attached to this Report as Exh. D. The table of results from this study is on page 102 of the paper.

10. The Stocking Study also applied the ASTM method E679 to calculate the geometric mean threshold odor level for the 57 participants at 15 ppb. The geometric mean provides only partial information on the impact of a contaminant on a population. The

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supplement and/or amend my opinions. I may use blow-ups of tables or charts from documents I have relied on as visual aids during my testimony at trial.

California Department of Public Health (CDPH) explained when it established a Secondary Maximum Contaminant Level (SMCL) for MTBE that:

Although the studies that investigated MTBE odor and taste present their results in terms of geometric means of the study panel, as well as lowest levels detected, the geometric means simply indicates that the 'average' person would sense MTBE at that level, based on the study's results in which half the panel reported sensing MTBE in drinking water at that level and half did not. The Department believes that in setting a drinking water standard, it should strive to meet a higher goal for public welfare protection than only half the population.

I agree with this statement regarding the limited value of geometric mean thresholds. A Copy of the CDPH Final Statement of Reasons In Support Of The Secondary Maximum Contaminant Level [of 5 ppb] is attached to this Report as Exh. E. See Final Statement of Reasons, at 9.

11. The Final Statement of Reasons given by CDPH when it set a standard of 5 ppb also supports my opinion in this case. CDPH is required by California Health & Safety Code § 116275(d) to apply secondary MCL levels to any contaminant that "may adversely affect the odor or appearance of the water and may cause a substantial number of persons served by the water system to discontinue its use, or that may otherwise adversely affect the public welfare." Final Statement of Reasons, at 10. In reaching its conclusion, CDPH specifically referenced the fact that 10 of 57 (18%) of panelists in the Malcolm Pirnie study detected MTBE at concentrations of 2 ppb. Final Statement of Reasons, at 10, 13. CDPH also specifically referenced the fact that in a 1997 study panelists detected MTBE at concentrations of 2.5 ppb, the lowest level tested.

12. I have reviewed the Expert Report of Harry Lawless, filed in another MTBE case. A copy of this Report is attached to this Report as Exh. F. Dr. Lawless expresses essentially the same opinion as mine - that MTBE can be detected in water at levels of 1-2 ppb by a significant

portion of the population, and that the portion of the population that could detect MTBE at these concentrations is approximately 10%. It is my opinion that Dr. Lawless's analysis, as expressed in his Expert Report, is largely correct. It certainly supports my opinion.

13. Another study that supports my opinion is a study conducted in 1997 by Yvonne Shen at the Orange County Water District. In this study, 6 of 24 panelists (25%) detected MTBE at concentrations of 2.5 ppb, the lowest level tested in the study. A copy of this study is attached to my Report as Exh. G. A number of people, including Dr. Lawless, have been critical of this study for various reasons, including the use of a relatively small panel. CDPH, however, relied at least in part on this study in adopting a SMCL of 5 ppb for California, and while I would not rely solely on this study to reach an opinion, the results of the study are consistent with my opinion.

14. Another study consistent with my opinion that humans detect MTBE in the range between 1 and 2 ppb is an industry-sponsored study (ARCO Chemicals, UK) that was performed by the Campden Food and Drink Research Association in 1993 (Campden I study). This study concluded that: "The concentration at which 70% of an experienced panel can detect the flavour of MTBE in water is between 0.04 and 0.06 ppb." (Campden I study, p. 4.) A copy of this Study is attached to my Report as Exh. H. A number of people, including Dr. Lawless, have been critical of this study because no confirmation of the actual test concentrations was performed. I found nothing in the study, however, to suggest that its reports of the concentrations were inaccurate. While I would not rely solely on this study to reach an opinion, the results in the study do corroborate my opinion.

15. Another source that supports my opinion is Lyondell's Product Safety Bulletin For Methyl Tertiary Butyl Ether (January 17, 2003). A copy of this Product Safety Bulletin is attached to my Report as Exh. I. Lyondell is a major manufacturer MTBE. Lyondell's Product Safety Bulletin for MTBE states: "MTBE presents a potential risk to groundwater supplies. Small amounts (by some accounts, in the below 1 part per billion range) of MTBE or gasoline blended with MTBE may impart an unpleasant and distasteful odor and taste to groundwater which can render such groundwater unsuitable for consumption." Exh. I, p. CAI FV 0527.

16. My opinion is also based upon well-established principles of taste and odor perception that suggest that the data in the studies upon which I rely are relatively conservative. For example, many studies have shown that olfaction and taste deteriorate with age (e.g., Stevens & Cain, 1993). The process begins in middle age and accelerates. Including older participants in a threshold study invites an elevated answer and increases the variability of the distribution.

17. Commercially sponsored studies conducted in England in 2003 and 2004 at the Campden lab (now called the Campden & Chorleywood Food Research Association Group) and observed by Dr. Irwin Suffet, an author of the Stocking Study, were unable to replicate the results of the Campden I study. One of the studies was simply inconclusive, and the other reported a high threshold level of which I was critical in an earlier Expert Report submitted for a different case. As explained above, however, geometric means thresholds have limited value. Dr. Lawless's Expert Report does a thorough job of explaining the limitations of the data and conclusions in the 2003 and 2004 Campden studies. For the reasons expressed in my earlier Report and in the Report of Dr. Lawless, the 2003 and 2004 Campden studies do not change my

opinion that a substantial number of people can detect MTBE at concentrations of 1 to 2 ppb, and that approximately 10% of people can detect MTBE in drinking water at concentrations of that magnitude.

#### IV. REFERENCES

California Code of Regulations (1997). Title 22. Final statement of reasons. Secondary maximum concentration level for methyl tertiary butyl ether and revisions to the unregulated chemical monitoring list. R-44-97. 20 pp.

Campden Food and Drink Research Association (1993). Flavour and Odour Thresholds of Methyl Tertiary Butyl Ether (MTBE) in water. Chipping Camden: UK. 8 pp.

Lawless, H. Expert Report, February 5, 2009. MTBE Products Liability Litigation. MDL No. 1358. Master File C.A. No. 1:00-1898 (SAS). City of New York v. Amerada Hess et al., 04 Civ. 3417.

Lyondell Chemical Company (2003). Product Safety Bulletin: Methyl Tertiary Butyl Ether. January 17, 2003. Revision 1. 90 pp.

Shen, Y. F., Yoo, L. J., Fitzsimmons, S. R., Yamamoto, M. (1997). Threshold odor concentration of MTBE and other fuel oxygenates. Report from the Orange County Water District, Orange California. 5 pp.

Stocking, A. J., Suffet, I. H., McGuire, M. J., and Kavanaugh, M. C. (2001). Implications of an MTBE odor study for setting drinking water standards. Journal AWWA, March, 95-105.

**Exhibit A**

**Cain CV, Including List of Publications**

# CURRICULUM VITAE

WILLIAM S. CAIN

## ADDRESS

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## BORN

September 7, 1941, New York City.

## EDUCATION

1968              Ph.D.    Brown University (Experimental Psychology)

1966              Sc.M.    Brown University (Experimental Psychology)

1963              B.S.     Fordham University

## ACADEMIC POSITIONS

1967-1972      Assistant Fellow, John B. Pierce Laboratory

1969-1970      Instructor in Epidemiology (Environmental Physiology), Yale University School of Medicine

1970-1976      Assistant Professor of Epidemiology (Environmental Physiology), Yale University School of Medicine

1972-1984      Associate Fellow, John B. Pierce Laboratory

1976-1984      Associate Professor of Epidemiology (Environmental Health) and Psychology, Yale University

1984-1994      Fellow, John B. Pierce Laboratory

1984-1994      Professor of Epidemiology (Environmental Health) and Psychology, Yale University

1994-          Professor of Surgery (Otolaryngology), University of California, San Diego

## PROFESSIONAL SOCIETIES

American Association for the Advancement of Science

American Psychological Association

American Water Works Association

Association for Psychological Science

Association for Chemoreception Sciences  
Human Factors and Ergonomics Society  
International Society of Indoor Air Quality and Climate

OTHER PROFESSIONAL AND ACADEMIC ACTIVITIES

Air & Waste Management Association

- Committee on Odors, TT-4: 1981-1986
- Committee on Indoor Air Quality, TT-7: 1981-1985

American Institute of Science and Technology

- Board of Trustees: 1982-1988
- Chairman of the Board: 1986

American Society of Heating, Refrigerating, and Air-Conditioning Engineers

- Committee on Gaseous Air Contaminants and Gas Contaminant Removal: 1971-1985; Vice Chairman, 1979-1980; Chairman, 1980-1981
- Committee on Ventilation for Acceptable Indoor Air Quality: 1978-1981; 1992-1998
- Task Group on Health and Safety: 1981-1983
- Committee on Ventilation and Infiltration: 1981-1990
- Committee on Criteria for Achieving Acceptable Indoor Environments: 1993-
- Steering Committee: IAQ '86, IAQ '93

American Society for Testing and Materials

- Committee D-22 on Sampling and Analysis of Atmospheres: 1989-1992
- Committee E-18 on Sensory Evaluation: 1992-1996

Association for Chemoreception Sciences

- Executive Chair: 1983-1984
- Executive Chair-Elect: 1982-1983
- Past Executive Chair: 1984-1985

Center for Indoor Air Research

- Scientific Advisory Board: 1991-1999

Fragrance Foundation Philanthropic Trust

- Vice President and Board of Directors: 1981-1986

Florida State University Sensory Research Institute

- Chairman, Technical Oversight Scientific Advisory Board: 1999-2004

International Society of Indoor Air Quality and Climate

- Co-chair, Task Force on Health Relevant VOC Measurements in Indoor Air: 1996-2005

Mayor's Commission for Science and Technology of the City of New York

-Member (ex officio): 1986

Monell Chemical Senses Center-Thomas Jefferson Univ. Chemosensory Clinical

Research Center

-External Advisory Committee: 1993-

National Academy of Sciences/National Research Council

-Committee on Odors from Stationary and Mobile Sources: 1978-1979

-Committee on Toxicological and Performance Aspects of Oxygenated Motor Vehicle Fuels:  
1996-1997

-Advisory Group for Strategies to Protect the Health of Deployed Forces: 1998-1999

National Institutes of Health

-Sensory Disorders and Language Study Section: 1991-1995

-Expert Panel on Smell, Taste, and Touch, and Chemosensory Disorders for the National  
Strategic Research Plan for the National Institute on Deafness and Other  
Communication Disorders: 1993

-Ad hoc member of various study sections and special emphasis panels: 1996-

National Institute for Occupational Safety and Health

-Indoor Environment Team, National Occupational Research Agenda (NORA): 1997-2001

New York Academy of Sciences

-President: 1986

-President-elect: 1985

-Vice President: 1983-1984

-Board of Governors: 1980-1988

Prix "Science pour l'Art" (Louis Vuitton/Moët Hennessy)

-North American Jury: 1991-1997

Research Institute for Fragrance Materials

-Clinical study advisory committee: 2004-

#### EDITORIAL DUTIES

Consulting editor, Sensory Processes: 1976-1981

Editorial board, Chemical Senses: 1982-1994

Editorial advisory committee, Indoor Air: 1989-1999

Editorial board, Indoor Air: 2005-

Editorial board, Physiology and Behavior: 1995-1996

Executive Editor, Chemosensory Perception: 2007-

## HONORS

Elected Fellow: Association for Psychological Science, American Psychological Association, American Society of Heating, Refrigerating, and Air-Conditioning Engineers, New York Academy of Sciences.

Crosby Field Award, American Society of Heating, Refrigerating, & Air-Conditioning Engineers, 1983

Javits Neuroscience Investigator Award (Claude Pepper Award), National Institute of Neurological and Communicative Disorders and Stroke, 1984

Master of Arts (privatum), Yale University, 1985

Sense of Smell Research Award, Fragrance Research Fund, 1986

Academy of Indoor Air Science, elected 1991

Max Muzell Award for Outstanding Achievement in the Chemical Senses, Association for Chemoreception Sciences, 2006

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2. Cain, W. S. & Engen, T. (1969). Olfactory adaptation and the scaling of odor intensity. In C. Pfaffmann (Ed.), Olfaction and Taste III (pp. 127-141). New York: Rockefeller University.
3. Cain, W. S. (1969). Odor intensity: Differences in the exponent of the psychophysical function. Perception & Psychophysics, 6, 349-354.
4. Cain, W. S. (1970). Odor intensity after self-adaptation and cross-adaptation. Perception & Psychophysics, 7, 271-275.
5. Stevens, J. C. & Cain, W. S. (1970). Effort in isometric muscular contractions related to force level and duration. Perception & Psychophysics, 8, 240-244.
6. Cain, W. S. & Stevens, J. C. (1970). Measurement of muscle fatigue by a constant-effort procedure. Résumés of 4th International Congress of Ergonomics, 21-22.
7. Cain, W. S. (1971). Physicochemical characteristics and supraliminal odor intensity: Reply to Mitchell. Perception & Psychophysics, 9, 478-479.
8. Cain, W. S. & Stevens, J. C. (1971). Effort in sustained and phasic handgrip-contractions. American Journal of Psychology, 84, 52-65.
9. Cain, W. S. & Marks, L. E. (Eds.). (1971). Stimulus & Sensation: Readings in Sensory Psychology. Boston: Little, Brown.
10. Stevens, J. C. & Cain, W. S. (1972). Effort in isometric contractions: Buildup and recovery. Proceedings of XVII International Congress of Applied Psychology (Liège, Belgium, 1971), Vol. I. Brussels: Editest, 399-407.

11. Marks, L. E. & Cain, W. S. (1972). Perception of intervals and magnitudes for three prothetic continua. Journal of Experimental Psychology, 94, 6-17.
12. Cain, W. S. (1973). Spatial discrimination of cutaneous warmth. American Journal of Psychology, 86, 169-181.
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14. Cain, W. S. (1973). Nature of perceived effort and fatigue: Roles of strength and blood flow in muscle contractions. Journal of Motor Behavior, 5, 33-47.
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and O. Valbjorn (Eds.), Indoor Climate: Effects on Human Comfort, Performance, and Health (pp. 257-269). Copenhagen: Danish Building Research Institute.

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**Exhibit B**

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William S. Cain, Ph.D.

Testimony in Legal Cases, 2006-2010

D. J. Nelson Trust dba Fruitridge Vista Water Co. vs. Atlantic Richfield Co., et al. Superior Court of the State of California, County of Sacramento. Deposition: 3/22/06. Attorney: John Yates, Baron & Budd, Dallas, TX.

Aaron Ochoa vs. MNP Automotive, inc. et al. Case No. 05CC10373. Superior Court of California, County of Orange. Deposition: 7/25/06. Attorney Thomas B. Connor, Anaheim, CA.

Mark H. Goldberg and Sherry R. Goldberg, et al. v. Louis Marson & Sons, et al., No. CV2004-008437. Superior Court for the State of Arizona, County of Maricopa. Deposition 09/08/06. Court testimony 09/16/08. Attorney Richard J. Woods, The Cavanaugh Law Firm, Phoenix, AZ.

County of Suffolk (NY) and Suffolk County Water Authority v. Amerada Hess, et al. No. 04 Civ. 5424, MDL No. 1358 (SAS). Deposition: 3/29-30/07. Attorneys: Carla Burke & John Yates, Baron & Budd, Dallas, TX.

Tonneson, et al. v. ExxonMobil Corp et al. No. 03 Civ. 8248, MDL 1358 (SAS). Deposition: 01/14/08. Attorney: Mike Axline, Miller, Axline & Sawyer, Sacramento, CA.

Robbie D. Bispo v. American Water Heater, et al. Case #05-CV-01223-PA, United States District Court, Northern California. Deposition: 5/14/08. Attorney J. Randolph Pickett, Pickett Dummigan Aguilar LLP, Portland, OR.

Pascoag Utility District v. ExxonMobil Corp., No. PC02-2437, Superior Court, County of Providence, State of Rhode Island. Deposition: 3/19/09. Attorney: William Dubanevich, Napoli, Bern, & Ripka, New York, NY.

Perry Expose et al., v. Southern Union Co, (d/b/a/ Missouri Gas Energy) et al. Case No. 9816-CV03603, Div. 15, Circuit Court of Jackson County, Missouri at Kansas City. Deposition: 9/29/09. Attorney: Rick D. Holtsclaw, Holtsclaw & Kendall, Kansas City, MO.

Village of Hempstead v. AGIP Inc., et al. No. 03-CV 10055, U. S. District Court, Southern District of New York. Deposition: 2/1/10. Attorney: Tate Kunkle, Napoli, Bern, & Ripka, New York, NY. Same deposition used for companion case, West Hempstead Water District v. AGIP Inc., et al. No. 03-CV 10052,

**Exhibit C**

**Case Specific Documents Reviewed**

1. Complaint for Damages, Crescenta Valley Water District v. Exxon Mobil et al, January 31, 2007, and amendment order regarding entry of Wortmann Oil Company, February 9, 2010.
2. Deposition of David S. Gould of Crescenta Valley Water District, April 6, 2010.
3. Customer Complaint Files CVWD MTBE 027746-028339, 06709-06758, 1589.

**Exhibit D**

**Stocking et al., Journal AWWA (2001)**

In early 2001, the US Environmental Protection Agency is expected to adopt a secondary maximum contaminant level (SMCL) for methyl tertiary butyl ether (MTBE) in drinking water. This article presents the first and only consumer study to determine the odor threshold of MTBE in drinking water. A protocol, based on the American Society for Testing and Materials method E679-91, was augmented to address concerns raised by interested stakeholders. The study, which was conducted according to the final odor threshold



protocol, used a panel of 57 consumers and yielded an odor threshold for MTBE in drinking water of 15  $\mu\text{g/L}$ . The 15  $\mu\text{g/L}$  threshold is the geometric mean of the individual thresholds for each of the 57 consumers. This consumer panel threshold is consistent with the trained panel thresholds reported from five other taste and/or odor studies, which ranged from 13.5 to 45.5  $\mu\text{g/L}$ . Consequently, the authors recommend using the methodology presented in this article as the scientific basis for establishing the federal SMCL for MTBE and other organic chemicals in drinking water.

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Implications of an

# MTBE odor study

for setting drinking water standards

**M**ethyl tertiary butyl ether (MTBE) has been used as a gasoline additive in increasing volume percentages since its introduction in 1979, when it was < 3% by volume. By 1998, MTBE was added to approximately 30% of the gasoline sold in the United States at approximately 11 to 15% by volume (USEPA, 1998). As a result of this widespread usage of MTBE and because of its unique physiochemical properties, it has been detected in some drinking water wells in areas with leaking underground storage tanks (Gullick & LeChevallier, 2000; Moran et al, 1999). Consequently, setting protective drinking water standards for MTBE has become an issue for regulatory agencies in federal and state governments.

As of January 2001, the US Environmental Protection Agency (USEPA) had not yet set any drinking water standards for MTBE. However, USEPA did issue an

advisory in December 1997 to provide guidance to communities whose water supplies had been affected by MTBE. The advisory recommended that "keeping the concentrations [of MTBE] in the range of 20 to 40 µg/L or below will likely avert unpleasant taste and odor effects" (USEPA, 1997), which suggests that MTBE is considered more of a taste and odor concern than a health concern. Currently, USEPA is considering the development of a formal secondary maximum contaminant level (SMCL) for MTBE; it is expected to be adopted in early 2001. The

establishment of an SMCL for MTBE would represent the first time that USEPA has developed an SMCL based on taste and odor for a specific synthetic organic chemical.

At the state government level, several states, including Maine, California, New Hampshire, and New Jersey, have set primary MCLs for MTBE. Maine and New Jersey have set MTBE MCLs of 35 and 70 µg/L, respectively, whereas in May 2000, California and New Hampshire adopted MCLs of 13 µg/L. All of these standards are based on protection of human health and not on aesthetic concerns. California is unique in setting an SMCL for MTBE based on the organoleptic characteristics of MTBE in water; it was adopted Jan. 7, 1999, at 5 µg/L. In contrast to the SMCLs of all other states, SMCLs in California are enforceable standards. The technical foundation for the California SMCL for MTBE was derived from (1) an estimation of the first concentration that could not be detected by any members of a testing panel (Young et al, 1996) and (2) the lowest concentration detected by any panelist in a study (Shen et al, 1998) that would not be subject to background laboratory MTBE interference during analytical measurement. This SMCL represented California's second attempt to establish an SMCL for a single organic compound. However, as the final statement of reasons for the MTBE SMCL illustrates, there is disagreement regarding the interpretation and application of these previous studies as they relate to drinking water standard-setting (Title 22 CCR, 1999).

#### SCOPE AND OBJECTIVE

Since 1996, five independent studies have been completed to determine the taste and odor thresholds for MTBE in drinking water (Shen et al, 1998; Dale et al, 1997; Young et al, 1996; APL, 1994; ARCO, 1993). Each

### METHYL TERTIARY BUTYL ETHER CONCENTRATIONS IN SAMPLES USED FOR THE ODOR TEST

2 µg/L  
3.5 µg/L  
6 µg/L  
10 µg/L  
18 µg/L  
30 µg/L  
60 µg/L  
100 µg/L

The concentrations were calculated using a 1.75 step factor:  
Concentration = 100 µg/L ÷ 1.75<sup>n-1</sup>, in which n is the dilution number.

of these studies used trained, expert panelists to elicit the threshold value for MTBE in drinking water. In light of the regulatory developments in California and elsewhere early in 1998, representatives of the regulatory and industrial communities believed that additional taste and/or odor data for MTBE should be developed using an untrained consumer panel—a group that was believed to reflect public sensitivities more accurately. To augment the five existing taste and odor studies, the Oxygenated Fuels Association commissioned a private consulting firm\* to organize a

consumer taste and/or odor study with a large sample population. Of critical importance in this process was the development of a methodology that would serve as a solid foundation for collecting threshold data that could be used to support an SMCL and also serve as a precedent for establishing future SMCLs for other organic chemicals.

The study's methodology, its results, and a discussion of the implications of these results for setting an SMCL for MTBE are presented here. The results and conclusions of this article are intended to be generally applicable; however, much of the discussion addresses the California experience in establishing SMCLs.

#### SMCL REGULATORY AUTHORITY AND GUIDANCE

In accordance with the Safe Drinking Water Act (SDWA) of 1974, as amended in 1986 and 1996, the US Congress directed USEPA to develop and enforce primary, health-risk based standards, or MCLs (USEPA, 1996). Under the SDWA, each state is given the option to (1) adopt the federal standards or (2) develop more stringent standards. Each state may also either (1) allow the federal government to retain enforcement responsibility or (2) take on the responsibility of enforcement from the federal government. Most states have chosen to locally enforce the federal standards.

In addition to primary MCLs, the SDWA required the federal government to establish aesthetic-based SMCLs for organic and inorganic chemicals in water. Again, most states have chosen to adopt the federal secondary standards; however, because of the aesthetic-based nature of these standards, they generally are not enforced by the federal or state governments. Thus, states neither require frequent monitoring for these chemicals nor do they levy

\*Malcolm Pirnie Inc., Oakland, Calif.

finer or take legal action when secondary standards are exceeded. In contrast, the California statute that addresses drinking water declares: "It is the intent of the Legislature to improve laws governing drinking water quality, to improve upon the minimum requirements of the federal Safe Drinking Water Act Amendments of 1996,..." (CHSC, 2000). Thus, California is one of the few states to establish several primary standards that are more stringent than corresponding federal standards, and it is the only state to enforce all secondary standards.

The SDWA provides several rules that must be followed when primary and secondary drinking water MCLs are established. Primary MCLs are based on protecting the population from exposure to individual chemicals and on chemical-specific health risk levels. These standards must conform to several sections of the SDWA, namely those titled Use of Science in Decision Making, Health Risk Reduction and Cost Analysis, Feasibility, and Subpopulations at Greater Risk (USEPA, 1996). The collective intent of these sections is to ensure that primary standards are scientifically supported, protective of the population, and technically and financially feasible.

However, the development and implementation of SMCLs is only vaguely described in federal regulatory language. Under the SDWA, a secondary drinking water standard is applied to any contaminant in drinking water that

may adversely affect the odor or appearance of such water and consequently may cause a substantial number of the persons served by the public water system providing such water to discontinue its use or may otherwise adversely affect the public welfare (USEPA, 1996).

The SDWA follows these criteria by noting "Such regulations may vary according to geographic and other circumstances" (USEPA, 1996). Thus, because of a lack of specific regulatory guidance for setting SMCLs (aside from the previous excerpts), states have significant latitude when establishing SMCLs.

On the basis of this guidance, USEPA has set many SMCLs for a variety of taste-, odor-, and color-causing constituents in drinking water since 1974 (Table 1). These regulated constituents are primarily inorganic chemicals (such as aluminum, iron, manganese) and general char-

TABLE 1 Federal secondary maximum contaminant levels

Regulated Constituent	Concentration/Level
Aluminum	0.05-0.2 mg/L
Chloride	250 mg/L
Color	15 color units
Copper	1 mg/L
Corrosivity	Noncorrosive
Fluoride	2 mg/L
Foaming agents	0.5 mg/L
Iron	0.3 mg/L
Manganese	0.05 mg/L
Odor	3 TON* units
pH	6.5-8.5
Silver	0.1 mg/L
Sulfate	250 mg/L
Total dissolved solids	500 mg/L
Zinc	5 mg/L

\*TON—Threshold odor number

acteristics of water (such as color, corrosivity, and odor), but the list does not currently include any individual organic chemicals. Currently, taste and odor in water from organic and inorganic sources are regulated federally and at the state level through use of the threshold odor number (TON), which is designed to represent the minimum number of sample dilutions required to achieve a detectable taste or odor in water. By definition, a TON of 1 indicates that if a sample is diluted at all,

the sample has no detectable odor to a trained assessor (*Standard Methods*, 1995). If a sample is assigned a TON of 3, for example, it indicates that the sample must be diluted to three times its initial volume to reach the lowest detectable concentration by a trained assessor. However, the TON method cannot guarantee an aesthetically acceptable water quality in many situations, especially those in which earthy, musty odors are present (McGuire et al, 1984). Thus, other methods such as the flavor profile analysis (FPA) were developed to protect consumers from taste and odor problems (Krasner et al, 1983).

#### BACKGROUND OF TASTE AND ODOR TESTING PROCEDURES

Taste and odor evaluation and quantification are continuing to evolve as an applied science (Suffert et al, 1999). The American Society for Testing and Materials (ASTM) and the American Public Health Association have developed procedures and practices that specify standardized applications of sensory methods. The methods use panels of measuring devices, which is analogous to the use of analytical instruments to quantify the concentration of specific chemicals. Taste and odor threshold concentrations for specific compounds in water are set using a threshold test as outlined in method 2150 for odor and method 2160 for taste (*Standard Methods*, 1995), as well as method E679-91 for odor (ASTM, E679-91).

The development of a taste and odor testing panel is fundamental to each of these methods because of the differences in individual sensitivity to compounds causing taste and odor problems. There are two types of panels for determining taste and odor thresholds—expert (or trained) panels and consumer panels. Expert panelists are people who have an increased sensitivity to odor. Although this may be desirable for regular monitoring for odorous substances in drinking water before the water is treated or distributed, it may skew the results of an odor threshold determination

TABLE 2 Summary of taste and odor results\*

Study	Type of Test	Temperature	Type of Water	Number of Panelists	Geometric Mean $\mu\text{g/L}$	Range $\mu\text{g/L}$
Shen et al, 1996 (paired comparison with known blank)	Odor	20°C	Odor-free	8†	13.5	2.5-100
	Odor	20°C	Odor-free	5	15.6	2.5-100
	Odor	20°C	Odor-free	5	40.3	15-100
	Odor	20°C	Odor-free	5	22.6	5-100
	Odor	20°C	Tap water	9	33.9	2.5-150
	Odor	20°C	Tap water	8	12.5	2.5-100
	Odor	20°C	Water with free Cl	7	43.5	15-150
	Odor	20°C	Water with free Cl	6	31.3	5-100
	Odor	40°C	Odor-free	5	25.2	15-150
	Odor	40°C	Odor-free	5	28.6	5-100
	Odor	40°C	Tap water	8	17.4	15-50
	Odor	40°C	Water with free Cl	7	20.9	2.5-50
	Odor	60°C	Odor-free	5	15.8	5.0-50
	Odor	60°C	Odor-free	5	45.4	2.5-100
Young et al, 1996 (paired comparison test)	Odor	40°C	Tap water	7	34	Min = 15
	Taste	25°C	Tap water	5	48	Min = 40
Study	Type of Test	Temperature	Type of Water	Number of Panelists	50% Probability of Correct Detection‡	Range $\mu\text{g/L}$
Dale et al, 1997 (triangle test)	Taste	25°C	Odor-free	9	24-37	NA§
	Taste	25°C	Colorado River water	9	24-68	NA
	Odor	25°C	Odor-free	9	43-71	NA
Study	Type of Test	Temperature	Type of Water	Number of Panelists	Arithmetic Average of Linear Regression $\mu\text{g/L}$	Recognition Range $\mu\text{g/L}$
ARCO, 1993 (triangle test)	Odor	25°C	Odor-free	6	Detection = 95 Recognition = 174	105-774
	Odor	25°C	Odor-free	6	Detection = 96 Recognition = 212	106-774
	Taste	25°C	Odor-free	6	Detection = 149	105-774
	Taste	25°C	Odor-free	6	Detection = 118	105-774
API, 1994 (triangle test)	Odor	25°C	Odor-free	7	Detection = 48 Recognition = 65	46-740
	Odor	25°C	Odor-free	7	Detection = 41 Recognition = 44	46-370
	Taste	25°C	Odor-free	7	Detection = 39	46-370
	Taste	25°C	Odor-free	7	Detection = 39	23-370

\*This table includes results from each of the tests in which there were four or more panelists. The number of panelists in the Shen et al. study has been estimated based on available information. This table does not contain results from the flavor profile analysis conducted by Dale et al (1997) because these results are not directly comparable to threshold results.

†Initially, 8 to 10 panelists were used during each session, but many of these panelists were not used to determine the geometric mean because of detection anomalies.

‡One standard deviation range

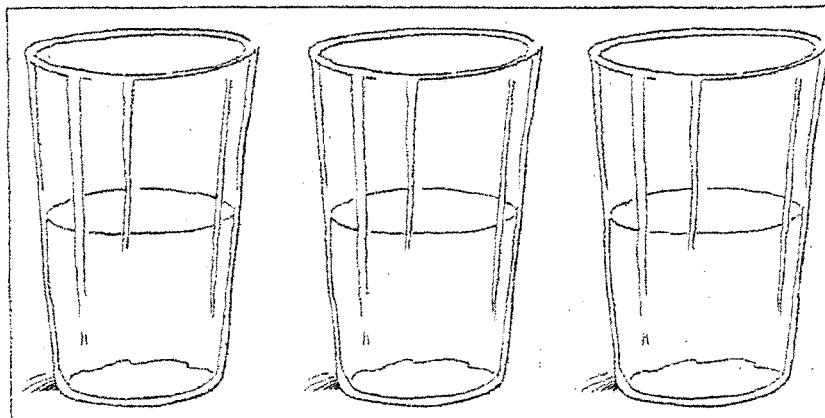
§NA—not applicable

study toward overrepresenting the more sensitive portion of the population. However, expert panelists are capable of characterizing and describing odors and thus should not be expected to guess whether a taste or an odor is present.

Alternatively, a consumer (untrained) panelist is only capable of determining whether multiple samples are dif-

ferent and is often required to guess which one of the samples is different. For example, in a forced-choice triangle test, such as that described by ASTM E679-91, a consumer panelist is forced to identify the different sample, even if he or she cannot detect a taste or an odor. The risk of false-positives is thus higher for a consumer

Sample solutions of 4 oz each were presented to the panelists in disposable 7-oz plastic cups that were determined by a consumer testing laboratory to be odor-free. Plastic cups were used instead of glass containers because glass containers often retain residual odors.



panel than it would be for a trained panel. The consumer panel test is designed to determine the detection threshold—the threshold at which a consumer can detect a difference but

cannot identify or characterize that difference. Regardless of the type of panel, it is important that the selected panelists be diverse in terms of age, gender, and ethnicity, as each of these factors can affect sensory perceptions.

Most odor studies use expert, trained panelists because of their familiarity with taste and odor testing protocol and the benefit that fewer panelists are necessary to determine a threshold. *Standard Methods* states that “when the results must represent the population as a whole or when great precision is desired [it is recommended that expert panels contain] not less than five persons, and preferably ten or more” (*Standard Methods*, 1995). As this statement implies, statistical analysis of the results from taste and odor studies is a complex issue, and it is particularly dependent on panel size and composition. Typically, threshold standards for various chemicals are determined

statistically representative of the entire state. Studies often attempt to circumvent this problem (and protect a larger percentage of the population) by choosing a panel that is more sensitive to the chemical of concern, which in turn elicits a lower taste or odor threshold value. If a panel consists of the most sensitive individuals within a population, then the taste or odor threshold value gives an estimate of the absolute minimum concentration detectable to the population.

The remainder of this article will focus specifically on the odor threshold study completed for MTBE and policy implications of that study.

#### PREVIOUS TASTE AND/OR ODOR STUDIES FOR MTBE

At least five taste and/or odor studies for MTBE in water have been completed (Shen et al, 1998; Dale et al,

In light of the regulatory developments in California and elsewhere early in 1998, representatives of the regulatory and industrial communities believed that additional taste and/or odor data for MTBE should be developed using an untrained consumer panel—a group that was believed to reflect public sensitivities more accurately.

using the geometric mean of the taste and odor thresholds from panelists' results—in which case, a panel of 8 to 10 trained panelists is usually sufficient (Mallevialle & Suffet, 1987; *Standard Methods*, 1995).

However, if an untrained consumer panel is used, additional panelists are needed to achieve scientifically valid results because of the likelihood of a much larger variability in each consumer's sensitivity (Mallevialle & Suffet, 1987). As more panelists are added, an individual panelist's results become less important, and there is a larger numeric confidence that the panelists' combined results are representative of some larger population under similar testing conditions. To statistically represent an even larger population, such as that of California, with any significant level of confidence is even more difficult because a panel must be formed that is sta-

1997; Young et al, 1996; API, 1994; ARCO, 1993). Each of these studies relied on published taste and odor standard methods as a basis for determining threshold detection values for MTBE (Table 2). Each of these studies used expert panelists to describe the odor associated with MTBE in water. The most frequently used descriptors to characterize the odor of MTBE were “sweet solvent” (Dale et al, 1997) and “estery, vanilla, and sweet” (Young et al, 1996). However, at concentrations > 20 µg/L, the descriptor “solvent” was used more frequently, and it was characterized at an increasingly greater intensity (Dale et al, 1997). The API (1994) and ARCO (1993) studies determined both detection thresholds (39–48 and 95–149 µg/L, respectively) and recognition thresholds (44–65 and 174–212 µg/L, respectively) for MTBE. The difference between a detection threshold and a recognition

TABLE 3 Consumer panel breakdown

Gender (57 total)		Age (57 total)		
Male number (%)	Female number (%)	18-29 number (%)	30-49 number (%)	50-65 number (%)
28 (49)	29 (51)	17 (30)	18 (32)	22 (38)

TABLE 4 Consumer testing laboratory\* quality control results

Target Concentration $\mu\text{g/L}$	Measured Concentration $\mu\text{g/L}$				
	Session 1†	Session 2	Session 3	Session 4	Session 5
Blank	ND‡	ND	ND	ND	ND
2.0	1.7	2.6	1.1 (1.0, 1.2)§	1.5	2.2
3.5	4.4 (6.1, 2.7)§	4.5	3.6	3.7	3.5
5	8.3	8.3 (10.2, 6.5)§	8.1	6.7	4.2
10	13.3	16.7 (17.4, 15.9)§	12.4	11.4	8.2
15	20.3	18.9	18	22.0	15.3
30	33.0	29.7	27.1	23.4	32.0
60	57.1	54.2	63.6	69.5 (44.5, 94.5)§	80.0
100	92.7	107.7	84	88.8 (64.5, 109.4)§	100.8 (77.4, 124.2)§

\*National Food Laboratory, Dublin, Calif.

†The water pH numbers for sessions 1, 2, 3, 4, and 5 were 7.43, 7.41, 7.23, 7.00, and 7.20, respectively.

‡ND—nondetect

§Average of replicate samples in parentheses

threshold is significant because, on the basis of regulatory experience, consumers will not complain about the quality of their drinking water until the recognition threshold is exceeded—that is, the point when they can describe the offending taste and/or odor. These two studies indicate that MTBE has a significantly higher recognition threshold than detection threshold.

In cases in which the respective published method failed to provide specific guidance on a procedure, each of the five studies made procedural assumptions, such as the type of water to use and the method of comparison. Moreover, several of the studies deviated from published procedures for analyzing data. ASTM method E679-91 states that the “best-estimate” threshold for any individual consumer is the geometric mean between the last miss and the first detection. First detection is defined as the concentration at which the consumer successfully detects all higher concentrations. Although data analysis techniques other than that described by method E679-91 may be more robust when taste and odor threshold data are analyzed, these analytical methods should be justified and peer-reviewed for application to taste and odor analysis prior to use.

However, both the ARCO and API studies presented results based on an alternative numerical analysis—an extrapolation of the data based on a linear regression of the data, assuming a lognormal distribution of the results. Using this alternative analytical technique, the thresholds from both of these studies resulted in detection thresholds higher than those of Shen et al (1998), Young et al (1996), and Dale et al (1997). As a result of these deviations from published methods or the methods of similar tests, the applicability of the ARCO and API results for setting SMCLs is questionable. To overcome this deficiency and confirm their results, the ARCO and API studies should have conducted retests at concentrations surrounding the reported odor threshold concentrations; however, this was not done.

#### SCOPE OF CONSUMER PANEL STUDY

To augment the results and avoid the noted deficiencies from the previous studies, the current study was undertaken (Malcolm Pirnie, 1998). The private consulting firm retained a consumer testing laboratory\* to organize the consumer panel and execute the sensory evaluation test. This consumer study was designed to be complementary to previous studies and to correct the main limitations of those studies, namely the size and makeup of their panels. Considerable effort was made to incorporate the experiences of the previous studies through discussions with some of the principal investigators of those studies. Following compilation of a draft protocol, the private consulting firm worked closely with members of the Association of California Water Agencies (ACWA) regarding recommendations for improvement.

To resolve inconsistencies among commentators, the stakeholders agreed to the formation of an expert advisory panel that consisted of Irwin H. Suffer and Michael J. McGuire—both past-chairmen of AWWA's Taste and Odor Committee—and Richard Berk of the University of California, Los Angeles—a statistician familiar with taste and odor study statistical analyses. Together, this panel incorporated all comments from ACWA, as well as verbal comments received from Steve Book of the California Department of Health Services (CDHS), in final-

\*National Food Laboratory, Dublin, Calif.

izing the protocol. Ultimately, the study protocol, including the procedure for statistical data analysis, followed ASTM method E679-91 primarily because E679-91 is a standard and well-accepted methodology that could be rigorously duplicated by other researchers.

#### PROTOCOL DEVELOPMENT

The final protocol was based on a consensus of the authors and Berk, and it was also deemed responsive to the ACWA comments. It was decided to conduct an odor study in lieu of a taste (flavor) study for two reasons: (1) it was thought an odor study would result in a lower threshold (Young et al, 1996), and (2) there were no laboratories available that would accept the liability of performing a taste (flavor) study without a primary MCL established by CDHS.

The ASTM method describes a forced-choice triangle test in which the consumer must choose one of three samples as being different from the rest. Although this inherently requires a panelist to guess, this triangle method

TABLE 5 ASTM\* threshold analysis

Dilution Number	Lowest Detected Concentration $\mu\text{g/L}$	Calculated Individual Threshold† $\mu\text{g/L}$
1	2	1.4
2	3.5	2.5
3	6	4.6
4	10	7.7
5	18	13
6	30	23
7	60	42
8	100	77
†	Missed 100	132

\*ASTM—American Society for Testing and Materials  
†A calculated individual threshold is the geometric mean between the lowest detected concentration and the next lowest concentration. In the case of 2  $\mu\text{g/L}$ , the next lowest concentration is 1  $\mu\text{g/L}$ . If a consumer panelist missed the highest concentration (100  $\mu\text{g/L}$ ), it was assumed that such a panelist would identify the next highest concentration (175  $\mu\text{g/L}$ ).

basis of EPA analysis, the authors also agreed that bottled water with < 500 mg/L total dissolved solids (TDS), as opposed to deionized or distilled water, was a neutral water that would neither mask nor enhance any MTBE odor in the samples. Room temperature (19.8–23.1°C [67.7–73.4°F]) was chosen by the authors as the operat-

Although setting the SMCL below 15  $\mu\text{g/L}$  would be even more restrictive because even

fewer consumers could detect MTBE, an SMCL set at such a level would have to be a public policy decision rather than a scientifically based decision.

was determined to be the best available published method. Although the ASTM method does describe many of the required details for performing an odor threshold study, there are a few aspects that it does not describe. These include

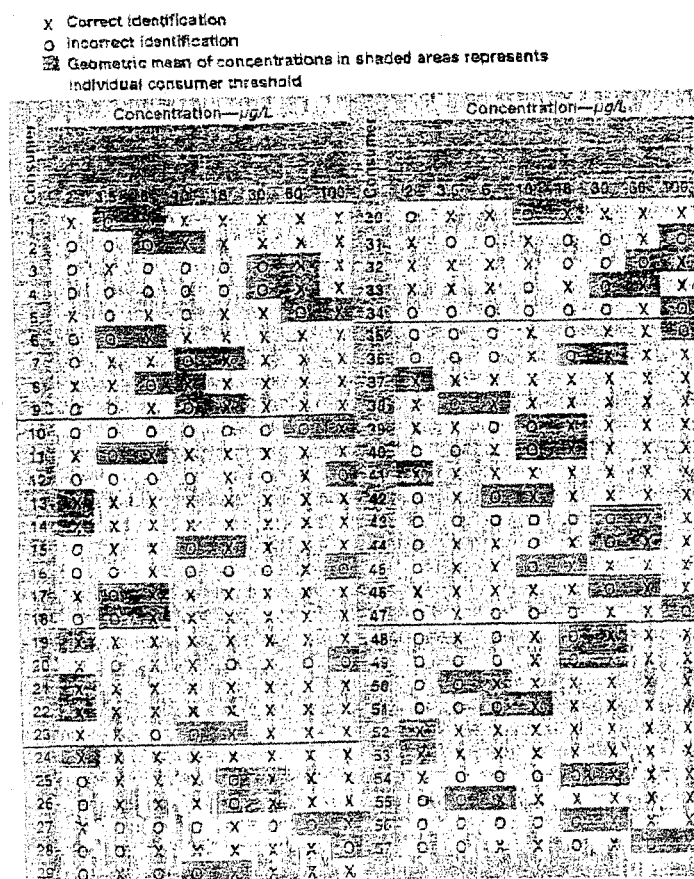
- the maximum number of trials that should be presented to a consumer,
- the type of water to use for the blanks,
- the sample presentation container, and
- the water temperature.

These details were addressed by the authors in cooperation with Berk, and a consensus was reached on each issue. The odor protocol used for this study involved presenting eight samples to the panelists in increasing MTBE concentrations (see sidebar, page 96), calculated according to a lognormal distribution. The MTBE and blank comparison solutions were prepared in odor-free bottled water at room temperature. The authors agreed that eight trials were the maximum number of trials to which a consumer could be exposed before olfactory fatigue began to affect the results (Matteiviale & Suffet, 1987). On the

ing temperature because it allowed this study to be comparable to other studies and it represented a temperature at which the public most often consumes drinking water.

Sample solutions of 4 oz each were presented to the panelists in disposable 7-oz plastic cups that were determined by the consumer testing laboratory to be odor-free. Plastic cups were used instead of glass containers because glass containers often retain residual odors. Each spiked and blank sample was covered with a clean watch glass. The panelists were instructed to lift each sample, swirl it several times, lift the watch glass, and smell the sample—as suggested in the EPA protocol (Krasner et al, 1983). The panelists were allowed to repeat a trial if they were uncertain after the first time. Once a trial was completed, the panelist replaced the watch glasses and signaled to the consumer testing laboratory staff that he or she was finished. The panelist then indicated on his or her individual scorecard the number of the sample that smelled different from the other two. If the panelist was not able to determine a difference, he or she was directed to guess which sample smelled different.

FIGURE 1 Individual consumer results from the threshold odor study



A key aspect of the protocol development was the composition of the panel. The original intention of this study was to use a large (50+) consumer panel. Although a consumer panel recruited from throughout California (through random-digit dialing techniques) may have been a stronger statistical representation of the California population, the authors and Berk acknowledged that this was not possible given the available budget, time frame, and logistical constraints of the study. Therefore, the test panel was recruited from a database of more than 10,000 consumers available from the consumer testing laboratory conducting the testing. Given the constraining circumstances, the authors and Berk decided that this database of consumers was sufficient to develop a consumer panel odor threshold.

Many of the consumers from the consumer testing laboratory's database had participated in previous sensory testing conducted by the laboratory that ranged from beer tasting to ice cream evaluations. The consumer test-

ing laboratory stated that only a few consumers in the database had done any type of drinking water evaluation in the past. The authors and Berk agreed that consumers recruited from this database should represent a cross-section of ages and genders from within a group of people who have not participated in sensory testing for at least one year prior to this study. The laboratory recruited the panelists according to these guidelines (Table 3). Consumers who smoked, were pregnant, or had been diagnosed as asthmatic were not used because the consumer testing laboratory wanted to limit potential auxiliary odors and liability concerns.

Once at the consumer testing laboratory's testing area, the consumers read and signed a disclosure statement and received a brief orientation that described the testing process. Before testing began, the laboratory conducted an example triangle test involving touching different grades of sandpaper to familiarize the panelists with the triangle test methodology. However, the consumers were not familiarized with the odor of MTBE because the authors felt that this would "train" the consumer panel, which is not desirable for consumer testing.

Because of size limitations of the consumer testing laboratory's testing facility, 5 sessions were conducted over two days, with 9 to 14 consumers present at each session. Between sessions, large fans were used to dissipate any fugitive MTBE odors present in the testing areas. The laboratory prepared fresh MTBE-spiked samples for each test session and prepared two split solutions for the subsequent quality assurance/quality control validation of the test concentrations. Gas chromatography/mass spectroscopy (GC/MS), USEPA drinking water method 524.2, was performed on all of the samples for each consumer panel. The results of the GC/MS analysis fell within the required range:  $\pm 40\%$  for values  $< 10$   $\mu\text{g/L}$  and  $\pm 20\%$  for values  $> 10$   $\mu\text{g/L}$  (Table 4), except for the few deviations noted.

## RESULTS

Once collected, data were analyzed according to ASTM method E679-91, which states that individual threshold concentrations are calculated by taking the geometric mean of the last concentration missed and the first concentration detected, given that all higher concentrations

were successfully detected (Table 5). If a panelist could detect all the concentrations presented, the threshold concentration for that panelist was the geometric mean of 2  $\mu\text{g/L}$  and the next lowest theoretical concentration (1  $\mu\text{g/L}$ ). If a panelist did not detect the highest concentration (100  $\mu\text{g/L}$ ), it was assumed that the panelist would have detected the next highest theoretical concentration and the threshold was calculated to be 132  $\mu\text{g/L}$  (the geometric mean of 100 and 175  $\mu\text{g/L}$ ).

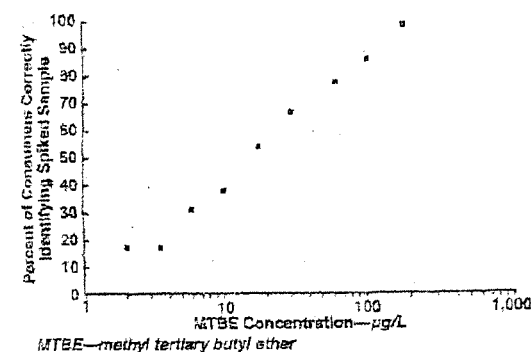
Results from each of the panelists are summarized in Figure 1. Individual calculated thresholds ranged from 1.4 to 132  $\mu\text{g/L}$ . The test panel geometric mean threshold was calculated to be 15  $\mu\text{g/L}$ , and it represents the threshold of approximately 50% of the consumers (assuming a lognormal distribution as shown in Figure 2).

### PREVIOUS ORGANIC CHEMICAL SMCLS

There is no precedent for applying these results to establish an SMCL. USEPA has not promulgated any SMCLs for organic chemicals. However, in Phase II of the National Secondary Drinking Water Regulations Proposed Rule (USEPA, 1989), USEPA considered setting SMCLs for several organic chemicals. In the Final Rule (USEPA, 1991), USEPA decided not to set these SMCLs because there was an inadequate experimental basis for setting SMCLs specific to organic chemicals. USEPA concluded with the statement: "Utilities are urged to find imaginative ways to meet the objective of having more pleasing odor characteristics for their finished water using the current 3-TON standard" (USEPA, 1991).

California established an SMCL for one organic chemical prior to MTBE, which serves as a case study in evaluating SMCL standard-setting protocols. The first organic chemical for which California established an SMCL was thiobencarb.\* Thiobencarb is a rice herbicide that is used primarily in the Sacramento River Valley. It breaks down during drinking water treatment to create a by-product with a bitter, pungent taste. The primary and secondary standards were set in 1987 for thiobencarb because the by-product was unidentified. The SMCL for thiobencarb was based on a consumer taste discrimination test (Stone & Sidel, 1983), in which 30 of the 51 panelists (59%) detected thiobencarb in water at 3  $\mu\text{g/L}$ . In addition, the results of a large consumer complaint database identified that complaints increased significantly when thiobencarb levels in untreated water exceeded 1  $\mu\text{g/L}$ . CDHS concluded that "organoleptic studies indicated that thiobencarb [sic] at a concentration of 3  $\mu\text{g/L}$  and above generates an off-taste in drinking water. These observations [sic], however, do not provide a maximum level at which the off-taste cannot be detected. In real-life situations, based on the number of complaints and the thiobencarb concentrations in the Sacramento River water, a statistically significant increase of complaints . . . [occurred] when thiobencarb was detected at 1  $\mu\text{g/L}$  near the intake to the Sacra-

FIGURE 2 Distribution of odor threshold results



mento River Water Treatment Plant." (California Proposed MCL for Thiobencarb, 1987).

Using both the consumer taste discrimination test and the consumer database, the SMCL for thiobencarb was set at 1  $\mu\text{g/L}$ . The second organic chemical for which California established an SMCL was MTBE. This SMCL was established at 5  $\mu\text{g/L}$ , based on an interpretation of the available taste and odor data for MTBE, as noted earlier (Title 22 CCR, 1999).

### POLICY IMPLICATIONS

Without specifically discussing whether the California SMCL was established at a justifiable level, past policy directions and the technical procedures used to arrive at the other SMCLs can be reviewed to determine a scientifically supportable SMCL for MTBE. As discussed in criterion A of the SDWA SMCL guidance, the purpose of SMCLs is to prevent a "substantial number of the persons . . . to discontinue [public water system] use" (USEPA, 1996). Pivotal to this statement is the reference to protecting a substantial number of people when SMCLs are set. There is no indication of whether the term "substantial" should represent 50, 75, or even 95% of the population.

To shed some light on the qualitative meaning of the word "substantial," one can examine the current TON standard. By definition, a trained assessor can detect a perceptible odor from water with a TON of 3 units. This suggests that the TON SMCL is not meant to protect the most sensitive individuals from objectionable tastes or odors in drinking water—rather, it is meant to protect a greater portion of the general population. If USEPA had defined "substantial" as protective of the most sensitive individuals, it would have selected a TON standard much lower than 3 to minimize taste and odor detection among consumers. The TON SMCL implies that there is an acceptable odor for drinking water.

\*Bolerio®, Valent USA, Walnut Creek, Calif.

In fact, none of the SMCLs currently approved were established to protect all consumers. Instead, a level was set that could generally be met by most water utilities but that would also ensure a high quality of water for the general population. For example, the federal SMCL for TDS is 500 mg/L; California has set an SMCL for TDS with an upper limit of 1,000 mg/L. Using a consumer panel, it was determined that water with a TDS level of 320–658 mg/L was identified as aesthetically “good,” water with a TDS level of 659–996 mg/L was identified as “fair,” and water with a TDS level of 997–1,332 mg/L was identified as “poor” (Bruvold et al, 1969). The fact that the federal and California SMCLs were established at a TDS concentration that was above the concentration detectable to consumers is illustrative of the compromises that are often made when SMCLs are set—an acceptable quality of water must be ensured for a substantial portion of the general population. Similarly, when trained panelists were used to evaluate the odor threshold for MTBE, the descriptor words suggested that at low concentrations (<15 µg/L) MTBE exhibits an odor that may not motivate a substantial number of consumers to discontinue use of their water supply.

Furthermore, all of the taste and/or odor studies for MTBE discussed in this article were completed in odor-free water. In practice, consumers would be exposed to MTBE in a natural water matrix that may enhance or mask the odor of MTBE. Experience from LaCrosse, Kan., where consumers were repeatedly exposed to MTBE concentrations > 100 µg/L without voicing complaints and elsewhere suggest that a natural water matrix with a high level of hardness or TDS can mask the odor of MTBE (California MTBE Research Partnership, 2000; MDHS, 1998). Thus, field data suggest that a consumer threshold concentration for MTBE in a natural water matrix will be greater than such a threshold in odor-free water.

Finally, in order to create a precedent for establishing future taste and odor standards for individual organic compounds, it is necessary to develop a reproducible approach for evaluating the quantitative results from threshold studies. The most conservative approach for evaluating threshold panel data would be to base the SMCL on the minimum value detected by any one panelist; however, there is no scientific precedent or technical foundation for this because it would only incorporate one individual's sensitivity to that specific compound. An alternative statistical analysis could also be performed; however, no methodologies for completing such an analysis of threshold data have been approved by ASTM or *Standard Methods*. The analytical option that has been approved and recommended by ASTM for evaluating threshold data is using the geometric mean of all panelists, which incorporates each panelist's sensory variability. In addition, the geometric mean is a reproducible and technically supportable statistic that serves as a foundation for an SMCL in the absence of other data, such as

the consumer database that was available in California for establishing the SMCL for thiobencarb.

The geometric means from the literature for MTBE in drinking water are as follows:

- from 13.5 to 45.4 µg/L (Shen et al, 1998) for odor,
- 34 µg/L (Young et al, 1996) for odor, and
- 48 µg/L (Young et al, 1996) for taste.

This study concluded that the geometric mean is 15 µg/L when a consumer panel is used. Thus, 15 µg/L represents a conservative approximation of the odor threshold for MTBE; this threshold is from a highly reproducible study that could be used as a scientifically justifiable basis for setting an SMCL. Furthermore, the use of 15 µg/L as the SMCL is consistent with past SMCL standard-setting approaches that are protective of many—but not all—consumers.

## SUMMARY AND CONCLUSIONS

Following the development and application of a methodology to determine the odor threshold of MTBE in water, the authors determined that this threshold is 15 µg/L. This concentration represents the lower range of the taste and odor threshold values obtained from the other five MTBE threshold studies. Thus, the methodology used in this study produces conservative results when compared with other analyses, and this study is reproducible. Consequently, the authors suggest that the methodology used in this analysis supports a reasonable scientific basis for establishing SMCLs for organic chemicals. In the absence of an alternative, formalized, peer-reviewed methodology for determining the threshold for a taste or odor test, the use of any other value for an SMCL would be unreliable and difficult to reproduce.

Following this argument, the authors believe that 15 µg/L is the only scientifically defensible value when the establishment of an SMCL for MTBE is under consideration. Although setting the SMCL below 15 µg/L would be even more restrictive because even fewer consumers could detect MTBE, an SMCL set at such a level would have to be a public policy decision rather than a scientifically based decision. Currently, there is no precedent for setting SMCLs that are protective of all consumers—an approach that would likely apply an increased burden on the regulated water utilities. Such an increased burden may not be commensurate with the benefits derived from attempting to avoid all negative consumer responses. In contrast to the thiobencarb case, there is no consumer complaint database to support any specific SMCL for MTBE below the geometric mean. Thus, the authors suggest that the logical and the only scientifically practical conclusion is to set an SMCL for MTBE at the geometric mean value.

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**Exhibit E**

**Final Statement of Reasons, Title 22, California Code of Regulations**

R-44-97.

**Final Statement of Reasons  
Secondary Maximum Contaminant Level for Methyl tert-Butyl Ether and  
Revisions to the Unregulated Chemical Monitoring List  
Title 22, California Code of Regulations**

All suppliers of domestic water to the public are subject to regulations adopted by the U.S. Environmental Protection Agency (EPA) under the Safe Drinking Water Act (42 U.S.C. 300f et seq.) as well as by the California Department of Health Services (Department) under the California Safe Drinking Act (Sections 4040.1 and 116300-116750, Health and Safety Code). California has been granted "primacy" for the enforcement of the Federal Act. In order to receive and maintain primacy, states must promulgate regulations that are no less stringent than the federal regulations.

In accordance with federal regulations, California requires public water systems to sample their sources and have the samples analyzed for inorganic and organic substances in order to determine compliance with drinking water standards, also known as maximum contaminant levels (MCLs). Primary MCLs are based on health protection, technical feasibility, and costs. Secondary MCLs are based on consumer acceptance, using parameters such as odor, taste, and appearance as measures of acceptability. The water supplier must notify the Department and the public when a primary or secondary MCL has been violated and take appropriate action. Public water systems must also sample for a number of "unregulated" chemicals, as set forth in regulation.

The Department proposes the following amendments to Chapter 15, Title 22 of the California Code of Regulations:

- To amend Section 64449, Article 16, to add the chemical methyl tertiary-butyl ether (MTBE) with a secondary maximum contaminant level (MCL) to Table 64449-A.
- To amend Section 64450, Article 17, to add ethyl tert-butyl ether (ETBE) and tert-amyl methyl ether (TAME) to Table 64450-B, limit MTBE unregulated chemical monitoring to nontransient-noncommunity water systems, and add Table 64450-D with perchlorate.
- To amend Section 64450.1, Article 17, to require monitoring at five-year intervals in conformance with federal regulations; eliminate obsolete deadlines; establish an appropriate date to use as criteria for grandfathered data for ETBE, TAME and perchlorate monitoring requirements; and make editorial corrections for text clarification.

The net effect is that:

- Community water systems would be required to monitor for MTBE to determine compliance with a secondary MCL, but would no longer be required to monitor MTBE as an unregulated chemical.

R-44-97

- Nontransient-noncommunity water systems would continue to monitor for MTBE as an unregulated chemical to determine if any contamination were present.
- Community and nontransient-noncommunity water system sources would be monitored for unregulated chemicals at five-year intervals.
- Vulnerable community and nontransient-noncommunity water system sources would be monitored for ETBE, TAME, and/or perchlorate to determine if any contamination were present.
- Water systems would be able to use ETBE, TAME and perchlorate data collected subsequent to January 1, 1993 toward initial monitoring requirement compliance.

The amendment, which would require unregulated chemical monitoring at five-year intervals, does affect California's primacy status in that it is a federal requirement and must be adopted into California's regulations. The other proposed amendments, with the exception of text clarification, would make the state's regulation more stringent than the federal, which is allowed. Therefore, these changes would not affect California's primacy status.

In addition to the above amendments, the Health and Safety Code citations in the authority/reference NOTES for sections 64449 and 64450.1 have been amended for consistency with the authority/reference NOTE updates. Further, section 64449(h) has been amended to use the technically correct reference to a subsection.

The following paragraphs describe and explain the proposed amendments.

#### Article 16. Secondary Drinking Water Standards 64449. Secondary Maximum Contaminant Levels

The purpose of this section is to list the chemicals for which secondary maximum contaminant levels (MCLs) have been established to protect the taste, odor and/or appearance of drinking water. Methyl tert-butyl ether (MTBE) would be added to this list with a secondary MCL of 0.005 mg/L.

MTBE is a colorless, liquid hydrocarbon that has been used as an octane booster in gasoline since the 1970s. Highly mobile in soils through which it rapidly migrates to groundwater, very soluble in water, and extremely slow to biodegrade (or possibly non-biodegradable), MTBE has been found in shallow groundwater throughout the U.S. Due to concerns regarding possible MTBE contamination of drinking water supplies in California, the Department added MTBE to the list of unregulated chemicals (22 CCR Section 64450) for which community and nontransient-noncommunity water systems are required to monitor in order to collect solid occurrence data for MTBE in drinking water sources. Data collected prior to and since the effective date of the requirement (February 13, 1997) by regional water quality control boards and drinking water utilities indicates there is some groundwater and surface water contamination in California. As of June 13,

R-44-97

1997, MTBE had been detected in 14 of the 388 systems that had monitored (26 sources). The Department is continuing to collect occurrence data and, at the same time, intends to establish appropriate drinking water standards for MTBE.

The Department has two concerns regarding MTBE from a public health standpoint: Risks to human health, and consumer acceptance of drinking water containing MTBE in terms of odor and taste. To address public health issues, the Department currently uses an action level of 35 micrograms per liter (ug/L), based on the non-carcinogenic effects seen in animal studies. This level was established in 1991 by the Pesticide and Environmental Toxicology Section which was then in the Department, but is now in Cal/EPA's Office of Environmental Health Hazard Assessment (OEHHA). At that time, there was very little known about the occurrence of MTBE in drinking water supplies. The action level provides non-regulatory guidance to the Department's Drinking Water Program, County Health Departments, utilities and the public about the significance of findings in drinking water of chemicals without drinking water standards.

In December 1996, EPA released a draft health advisory of 70 ug/L, based on kidney and liver effects observed in laboratory animal experiments for MTBE ("Methyl-t-Butyl Ether [MTBE] Drinking Water Health Advisory, Health and Ecological Criteria Division, Office of Science and Technology, Office of Water US EPA, Washington, D.C. 20460).

OEHHA is reviewing the available health effects data on MTBE in order to establish a protective public health level; subsequently, the Department will propose a primary drinking water standard.

Due to its chemical properties, MTBE can be both smelled and tasted by many people at levels below both the federal and state health advisory levels discussed above. Therefore, to address the potential adverse affect of MTBE on the aesthetic quality of water, the Department has determined that a secondary MCL should be established. Under California regulations, violations of secondary MCLs require public notification and treatment. Under certain circumstances, a water utility may be able to qualify for a waiver, but to date, waivers have only been granted for existing water systems with iron and manganese problems. Adoption of a secondary MCL for MTBE would ensure that consumers are not exposed to drinking water with objectionable taste and odor related to MTBE contamination and would also ensure that MTBE levels are below current, and presumably future, health-based advisory levels.

Only two MTBE taste and odor studies have been conducted. A Great Britain study evaluated the taste and odor of a number of drinking water contaminants including MTBE ("Taste and Odour Threshold Concentrations of Potential Potable Water Contaminants", by W.F. Young, H. North, R. Crance, T. Ogden, and M. Arnott, *Water Research*, Volume 30, Number 2, 1996, pages 331-340). In this study, a panel of 9 specially selected and trained odor and taste assessors (females between ages 25 and 55) were used to evaluate known concentrations of MTBE dissolved in water. MTBE was prepared in different concentrations, diluted 2.5- to 3-fold between concentrations. Concentrations of chemicals in this study were over a 2000-fold range.

R-44-97

Results were presented in terms of the threshold concentration, that is, the lowest concentration in water for which an assessor detected an odor or taste. Rather than a simple average, the authors used the geometric, "because of the geometric interval between dilutions of concentrations and, as the best estimate, it assumes a normal distribution of sensitivities to give 50-50 divisions of a population." The lowest concentration detected by panelists was also presented. For odor detection, the average (geometric mean) threshold MTBE concentration was 34 ug/L (7 of 9 panelists; 78 percent) and the lowest concentration was 15 ug/L (3 of 9 panelists; 33 percent). For taste detection, the average (geometric mean) threshold MTBE concentration was 48 ug/L (5 of 9 panelists; 56 percent) and the lowest was 40 ug/L (4 of 9 panelists; 44 percent).

In summary, the thresholds for odor and taste of 15 and 40 ug/L, respectively, were detected by a sizable proportion of the assessment panel (33 and 44 percent). The methods of the study and the reported findings indicate that at the next lower concentration, estimated at 5 and 12.5 ug/L for odor and taste, respectively, no MTBE was detected by the assessors.

The Orange County Water District in California also performed a study on threshold odor concentrations of MTBE. The results of the study, "Threshold Odor Concentrations of MTBE and Other Fuel Oxygenates" by Y.F. Shen, L.J.Y. Yo, S.R. Fitzsimmons, and M.K. Yamamoto, was presented at a national meeting of the American Chemical Society in San Francisco in April 1997. They found geometric means of 13.5 to 43.5 ug/L, indicating that half of the panelists detected MTBE at those levels. The geometric means odor thresholds were of the same magnitude, regardless of water type (odor-free water, chloraminated tap water, or water containing free chlorine) or temperature (room temperature, 40°C, or 60°C).

The lowest MTBE concentrations in water at which odor was detected among the various test runs were 2.5, 5, and 15 ug/L. The lowest threshold of 2.5 ug/L occurred in 7 (44 percent) of 16 test runs combining water types and temperatures. A lowest odor threshold of 5 ug/L was reported in 4 tests (2.5 percent) and 15 ug/L was reported in 5 tests (31 percent). The 2.5-ug/L odor threshold was reported in: (a) 2 of 4 runs in odor free water at room temperature, and 1 of 2 at 60°C; (b) 2 of 2 runs in tap water at room temperature, and 1 of 1 run at 60°C; and community 0 of 2 in water with free chlorine at room temperature, and 1 of 1 at 40°C.

In summary, the Shen *et al* study shows that MTBE odor may be detected at levels as low as 2.5 ug/L. No lower concentration was tested. Hence, the highest concentration that would not be detected under conditions of this study is unknown, but less than 2.5 ug/L.

Shen, *et al*, also investigated MTBE in the laboratory to check for cross contamination of laboratory samples, which is of concern since MTBE is used as a common laboratory extraction solvent. They found "background" concentrations of MTBE ranging from 0.07 to 3.12 ug/L (average 0.93 ug/L) in 40 vials containing deionized water that had

R-44-97

been placed throughout the laboratory for an unspecified period of time. This suggests that detecting very low levels of MTBE in water may be confounded by MTBE in the laboratory, which is why the Department established a detection level for the purposes of reporting (DLR) of 5 ug/L at the time that it adopted the MTBE unregulated chemical monitoring requirement.

Since MTBE's odor is detected at a lower concentration than its taste, odor is the appropriate endpoint for establishing the secondary MCL. The Department believes the study by Young *et al.* is the most appropriate for establishing the secondary MCL because it was a large study of a number of chemicals which would hopefully preclude any unintended bias that could be associated with a study focused on fuel additives conducted in a highly politicized situation. Therefore, the Department proposes a secondary MCL of 5 ug/L (0.005 mg/L) for MTBE. In addition, because of the possibility of MTBE cross-contamination in analytical laboratories, the Department believes an MCL of 5 ug/L would provide adequate protection of consumers from adverse odors (and, therefore, taste) while sparing drinking water systems from MCL violations based on spurious laboratory results resulting from laboratory contamination.

Although, as noted above, MTBE has been detected in some California drinking water supplies, at this time, there do not appear to be any active drinking water sources that would be out of compliance with the proposed MTBE secondary MCL.

The Department proposes to correct a typographical error in subsection 64449(i). The published text shows an underline (" \_ ") preceding "pH"; the space immediately preceding should be blank.

#### Article 17. Special Monitoring Requirement for Unregulated Organic Chemicals

##### 64450. Unregulated Chemicals

The purpose of this section is to list those chemicals for which monitoring must be conducted to determine their occurrence in drinking water supplies. The proposed regulation would amend this section in several ways: Add ethyl tert-butyl ether (ETBE) and tert-amyl methyl ether (TAME) to Table 64450-B, limit unregulated chemical monitoring for MTBE to nontransient-noncommunity water systems, and add Table 64450-D for inorganic chemicals with perchlorate listed.

Due to the concerns related to oxygenates used in reformulating gasoline, the Department is proposing to add ETBE and TAME to the unregulated monitoring section in order to collect occurrence data in California. These oxygenates, particularly ETBE which is not known to be in current use in California, are much less likely to be found in water than MTBE. However, there is still some potential for occurrence and this risk might increase in the future due to the many issues that have been raised related to MTBE that might result in its use being curtailed. TAME is known to be in current use by one refinery in some of its reformulated gasoline at 2 percent TAME to 9 percent MTBE. When used,